DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 1 2000

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The Honorable John J. Duncan, Jr.
House of Representatives
Washington, D.C. 20515-4202

Dear Mr. Duncan:

Thank you for your letter of July 31, 2000, on behalf of your constituent, Ms. Kellie Moths of Louisville, Tennessee. Ms. Moths has a child with serious food allergies. She is concerned that insufficient labeling of food products may pose a threat to people with allergies. She is particularly concerned that an allergen may be included in a food but declared under the term "natural flavorings." She would like companies to indicate on the label if the product contains a major food allergen. She would also like restaurants to list the ingredients of the foods they serve.

The Food and Drug Administration (FDA or the Agency) shares Ms. Moths' concerns about the need to inform consumers of allergenic substances in food. Being able to identify and avoid allergens is of great importance to people with food allergies.

FDA addressed its concerns about the labeling of allergenic substances in food in a Notice to Manufacturers (copy enclosed) that was distributed to food manufacturers, trade associations, and other food industry groups. It advises the industry on the steps it should take to ensure that allergens are declared on food labels. It asked manufacturers to examine their product formulations for known allergens and to be sure to declare the presence of these ingredients in the ingredient statement on the label.

In its ongoing efforts to protect the public health, FDA's staff at the Center for Food Safety and Applied Nutrition (CFSAN) have been actively engaging in dialogue with industry and consumer groups to raise awareness about the presence of allergens in foods to identify practical approaches to the

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labeling of allergens. They have also been considering how to revise the labeling regulations to ensure that sensitive individuals are protected and that manufacturers fully understand the circumstances in which allergens must be declared. In addition, CFSAN is currently reviewing a petition that raises concerns similar to those of Ms. Moths. We have forwarded your correspondence to the docket for this matter for inclusion in the record. (Docket #00P-1322) Please be assured that we will consider all comments before making a final decision on this issue.

By way of background, the Federal Food, Drug, and Cosmetic (FD&C) Act requires, in virtually all cases, that labels of food fabricated from two or more ingredients bear a declaration of each ingredient, by its common or usual name, in descending order of predominance by weight in the ingredient statement. There are two very narrow exemptions from this ingredient labeling requirement. The first one is provided in section 403(i) of the FD&C Act. That section states that spices, flavorings, and certain colorings may be declared collectively without naming each one. The second one is provided in Title 21, Code of Federal Regulations § 101.100(a) which states that incidental additives, such as processing aids that are present at insignificant levels and that do not have a technical or functional effect in the finished food, do not have to be declared on the label.

Regarding your constituent's suggestion that restaurants list ingredients on the menu, we believe it may be feasible for certain types of restaurants (e.g., chain or fast food restaurants with standardized food preparation and ingredient specifications) to provide ingredient information. However, at this time the Agency does not have enough information about the industry to determine the appropriateness and manner of requiring ingredient labeling by restaurants. While we do not have requirements for ingredient labeling of restaurant foods, FDA encourages such declarations on a voluntary basis. We believe that a brochure could be helpful to consumers in providing information on ingredients used in prepared foods when it is impracticable for a restaurant to provide ingredient information for all menu items. Thus, the Agency encourages restaurants to provide such information when

practical. As we develop our policy on the use and labeling of allergens, we will consider the appropriateness of requiring labeling of allergenic substances present in restaurant foods.

Thanks again for contacting us regarding this matter. If you have further questions, please let us know.

Sincerely,

Kristine Harper

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

cc: Dockets Management Branch (HFA-305)

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
June 10, 1996

NOTICE TO MANUFACTURERS

Label Declaration of Allergenic Substances in Foods

This letter is to make you aware of the Food and Drug Administration's (FDA's) concerns regarding the labeling of foods that contain allergenic substances. Recently, FDA has received a number of reports concerning consumers who experienced adverse reactions following exposure to an allergenic substance in foods. These exposures occurred because the presence of the allergenic substance in the food was not declared on the food label.

The Food, Drug, and Cosmetic Act (the act) requires, in virtually all cases, a complete listing of all the ingredients of a food. Two of the very narrow exemptions from ingredient labeling requirements appear to have been involved in a number of the recent incidents, however. First, section 403(i) of the act provides that spices, flavorings, and colorings may be declared collectively without naming each one. Secondly, FDA regulations (21 CFR 101.100(a)(3)) exempt from ingredient declaration incidental additives, such as processing aids, that are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food.

In some of the instances of adverse reactions, failure to declare an ingredient appears to have been the result of a misinterpretation of the exemption from ingredient declaration provided for incidental additives in 101.100(a)(3). FDA reminds manufacturers that to qualify for the exemption from ingredient declaration provided for incidental additives and processing aids, a substance must meet both of the requirements of 101.100(a)(3), i.e., it must be present in the food at an insignificant level, and it must not have any technical or functional effect in the finished food. Thus, incidental additives may include substances that are present in a food by virtue of their incorporation as an ingredient in another food. However, when an ingredient added to another food continues to have an effect in the finished food (e.g., egg white as a binder in breading used on a breaded fish product), the ingredient is not an incidental additive, and its use must be declared on the label.

The recent adverse reaction reports indicate that some manufacturers have also incorrectly interpreted what constitutes an insignificant level of a substance. Clearly, an amount of a substance that may cause an adverse reaction is not insignificant. Because evidence suggests that some allergenic substances can cause serious allergic responses in some individuals upon ingestion of very small amounts of the substance, it is unlikely that such an allergen, when it is present in a food, can be present at an insignificant level. Thus, it follows that the

requirements of 101.100(a)(3) can not be met under such circumstances.

FDA is considering whether it is necessary to clarify its regulations to ensure that manufacturers fully understand the circumstances in which allergenic food ingredients must be declared and to ensure that sensitive individuals are protected by appropriate labeling.

We have also received reports of adverse reactions to foods in which likely allergenic substances were used as flavors, and not declared by name. Therefore, in addition to the exemption in 101.100(a)(3), the agency is also considering whether an allergenic ingredient in a spice, flavor, or color should be required to be declared, 403(i) not withstanding. On a substance-by-substance basis, the agency has required ingredients covered by the exemption in section 403(i) to be declared when necessary to protect individuals who experience adverse reactions to the substance, e.g., FD&C Yellow No. 5. The agency is open to suggestions on how to best address this problem.

While FDA has not formally defined "allergens," it provided examples of foods that are among the most commonly known to cause serious allergenic responses, i.e., milk, eggs, fish, crustacea, mollusks, tree nuts, wheat, and legumes (particularly peanuts and soybeans), in a policy statement dealing with foods derived from new plant varieties published in the FEDERAL REGISTER of May 29, 1992 (57 FR 22984 at 22987).

FDA advises that the issue of declaring allergenic ingredients in food is being discussed on an international level. Several individual governments and the Codex Alimentarius Commission have begun to formulate policy for the labeling of foods containing allergenic ingredients to ensure that consumers are provided sufficient information to avoid substances to which they are allergic. While packaged foods sold in the U.S. are among the most comprehensively labeled foods in the world (some countries provide broader exemptions from ingredient declaration), FDA is studying its labeling requirements, and considering whether rulemaking is necessary, for the labeling of allergenic ingredients.

While the agency does so, FDA asks manufacturers to examine their product formulations for ingredients and processing aids that contain known allergens that they may have considered to be exempt from declaration as incidental additives under 101.100(a)(3), and to declare the presence of such ingredients in the ingredient statement. Where appropriate, the name of the ingredient may be accompanied by a parenthetical statement such as "(processing aid)" for clarity.

The voluntary declaration of an allergenic ingredient of a color, flavor, or spice could be accomplished by simply naming the allergenic ingredient in the ingredient list. Because such ingredients are normally present at very low levels, the name of the ingredient could generally be placed at the end of the ingredient list and be consistent with its descending order of predominance by weight. Other, non-allergenic ingredients t hat are exempt from declaration would remain unlisted.

Another area of concern is the potential, inadvertent introduction of an allergenic ingredient to a food (e.g., in a bakery that is manufacturing two food products on one production line, one product with peanuts and one without, where traces of peanuts, or peanut products, may

end up in the product that does not normally contain peanuts). FDA is considering options for providing consumers with information about the possible presence of allergens in these foods.

The agency is aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (insert name of allergenic ingredient)." FDA advises that, because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMP. The agency urges manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of the identified food. The agency is open to suggestions on how best to address this issue.

Sincerely,

Fred R. Shank, Ph.D.

Director, Center for Food Safety and Applied Nutrition

Home

Hypertext maintained by LRD, DMS, et. al. (last updated on 5/30/97)

JOHN J. DUNCAN, JR.
2D DISTRICT, TENNESSEE
2400 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-4202
PHONE: (202) 225-5435
FAX: (202) 225-6440

800 MARKET STREET
SUITE 110
KNOXVILLE, TN 37902
PHONE: (865) 523-3772
FAX: (865) 544-0728

262 E. BROADWAY
MARYVILLE, TN 37804-5782
PHONE: (865) 984-5464
FAX: (865) 984-0521

6 E. MADISON AVENUE
COURTHOUSE
ATHENS, TN 37303-4297
PHONE: (423) 745-4671
FAX: (423) 745-6025

Congress of the United States
House of Representatives
Washington, DC 20515-4202

July 31, 2000

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Dr. Jane E. Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852-1750

Dear Dr. Henney:

I was recently contacted by Ms. Kellie Moths, a member of my constituency. Ms. Moths is concerned about the lack of information regarding food allergens in products containing "natural flavorings" and in restaurants. She would like to see stronger labeling standards.

I would appreciate it if you could provide me with additional information on the labeling requirements for such foods so that I might better be able to respond to Ms. Moths' concerns. I am also interested in FDA's analysis of this issue and the potential impact of stronger standards in this area.

Likewise, I am sure Ms. Moths would appreciate FDA's careful consideration of this matter.

Thank you for your time and attention. If I can be of any possible assistance, please do not hesitate to let me know.

With kindest regards, I am

Sincerely,

JOHN J. DUNCAN, JR.
Member of Congress

JJD:jm

Enclosure

00-5189

PRINTED ON RECYCLED PAPER

(865) 983-1080

RECEIVED
JUL 3 2000
Hon. John J. Duncan, Jr.

June 27, 2000

Kellie Moths
3686 Channel Drive
Louisville, TN 37777

CHANGING THE FDA LAWS REGARDING FOOD ALLERGIES

Dear Congressman Duncan,

My name is Kellie Moths. I am a teacher in the Blount County School System. But, most importantly, I am the mother of a 4 year old child with life-threatening food allergies.

I am writing to you for your help. Just like people in wheelchairs, those who are blind, and those who suffer from MS, just to name a few, food allergies are a significant disability. This disability has affected our family in tremendous ways. Food is a major necessity in life and we become at companies' mercy when buying food for our child. Foods that list "Natural Flavorings" have to be avoided because they could contain less than 2% of a life-threatening allergen which is the present law. When I contact companies, more than not, tell me to just assume they do contain one of my son's life-threatening allergens. When I ask them to write me a letter stating their response to me, they say they will, but never do. The sad part is, legally they don't have to tell me anything. I am told by the FDA and The Food Allergy Network the very soonest any changes will take place is the year 2005. The only way any changes can happen before then is for you to help change the laws now.

Here is what I would like:

1.Have all companies who list "Natural Flavorings" on their products to list the major food allergens. For example: THIS PRODUCT CONTAINS: Cow's milk, Peanuts, Tree Nuts, Shellfish, Wheat, Gluten, Soy, Eggs. (These are the major food allergens.)

2. Make ALL restaurants list ingredients of products they serve.

This is another major battle we face. 5% out of 100% will even discuss whether we could eat at their establishment. They won't even help with an ingredient list I could read or truly want to be inconvenienced with me or my son. The only looser as we walk out the door is my son. What a shame!

Children are dying from food allergies! This issue needs to be taken seriously and become a top priority. Can I please depend on you to help those suffering from food allergies and change the present laws?

Respectfully,

Kellie Moths

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